REMARKS

Claims 32-40, and 42-43 are pending in the subject application. By this Amendment, applicants have amended claims 38, 39, and 40, and have added new claims 46 and 47. Applicants maintain that the amendments to the claims raise no issue of new matter. Claims 38 and 39 have been amended merely to correct their dependency. Support for the amendments to claim 40 can be found in the specification at, *inter alia*, page 3, lines 8-12; page 7, lines 26-29; page 9, lines 30 to 34; page 1, lines 20-24; page 6, lines 4-14; and page 10 lines 10 and 17. Support for new claim 46 can be found in the specification at, *inter alia*, page 3, lines 27-29; and page 5, line 32 to page 6, line 14. Support for new claim 47 can be found in the specification at, *inter alia*, page 3, lines 8-12; page 1, lines 20-24; page 6, lines 4-14; and page 10 lines 10 and 17. Accordingly, applicants respectfully request entry of this Amendment. After entry of this Amendment, claims 32-40, 42-43, and 46-47 will be pending and under examination.

Claim Rejections under 35 U.S.C. §103(a)

In the May 5, 2004 Office Action, the Examiner stated that claims 32-40, 42 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. (Patent No. 4,816,563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86). The Examiner further stated that Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The Examiner stated that Ablashi et al. do not teach to use cell free product secreted from a mammal, which contains the antigen specific TF against HSV-6 or HSV-5, but that Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from colostrum or milk of

a bovine.

The Examiner further stated that it would have been obvious for a person skilled in the art at the time the application was filed to be motivated by Ablashi et al. and Wilson et al. to use the TF derived from the milk or colostrum product for treating CFS because the TF derived from a mammal milk product would be much easier and more economical to be accepted by patients or the market. The Examiner stated that hence the claimed invention as a whole is prima facie obvious absent unexpected results. The Examiner further stated that applicants' previous response argued against the references individually.

In response, applicants respectfully traverse the Examiner's rejection. Initially, applicants note that in their response filed December 2, 2003, applicants argued against the references in combination, not individually, noting that Ablashi et al. did not teach the invention, and Wilson did not cure the deficiency (i.e. Wilson and Ablashi in combination did not teach the invention). However, applicants wish to clarify that Ablashi et al., when combined with Wilson et al. as suggested by the Examiner, do not teach a cell free fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6A infected lactating mammal as claimed by applicants in claims 32, 34, 36, 38, 40 and 42. Neither Ablashi et al. or Wilson et al. teach a HHV-6A subtype specific transfer factor, therefore no combination of Albalshi et al. and Wislon et al. can do so. Ablashi et al. disclose a spleen-derived general transfer factor for a combination of EBV, HHV-6 and CMV. Wilson et al. do not disclose an HHV-6A specific transfer factor.

Similarly, no combination of Wilson et al. and Albashi et al. teach a cell free fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6B infected lactating mammal as

claimed by applicants in claims 33, 35, 37, 39, 41 and 43. Neither Ablashi et al. or Wilson et al. teach a HHV-6B subtype specific transfer factor, therefore no combination of Albalshi et al. and Wislon et al. can do so. Ablashi et al. disclose a spleen-derived general transfer factor for a combination of EBV, HHV-6 and CMV. Wilson et al. do not disclose an HHV-6B specific transfer factor.

With regard to newly added claim 46, applicant notes that neither Ablashi et al. or Wilson et al. teach an amount of a cell-free fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6A immunized lactating mammal and an amount of a cell-free fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6B immunized lactating mammal effective to treat chronic fatigue syndrome in a human subject. Therefore, no combination of Albalshi et al. and Wislon et al. can do so. Ablashi et al. disclose a spleen-derived general transfer factor for a combination of EBV, HHV-6 and CMV. Wilson et al. do not disclose either a HHV-6A or a HHV-6B specific transfer factor.

The Examiner further stated that "the effectiveness of using same product or obviousness of same product from the 50% shown by the prior art vs. 90% effective of present invention does not mean that the composition disclosed by the prior art is patentably different from the claimed composition. Therefore, it cannot be considered as an unexpected result."

With regard to claim 40, and in response to the contention that the product of Ablashi et al. is the "same product" as applicants' claimed invention, applicants do not understand which point the Examiner is making. The rejection is on the grounds of obviousness. Therefore, there is clearly no "same product" comparison. To the extent that the Examiner acknowledges that the

rejection is on the ground of obviousness, i.e. different products are being compared, there is no suggestion in either prior art reference, or both combined, that better than 50% efficacy can be achieved. Therefore, it is surprising that 90% efficacy has been achieved.

Furthermore, applicants note the §102(b) references cited by the Examiner in the May 5, 2004 Office Action teach against the Examiner's position that a transfer factor for EBV, HHV-6, and CMV is the "same product" as a transfer factor specific for HHV-6 subtypes. Applicants note that the Fall 1997 edition of "Positive Health News" cited by the Examiner discloses the product "Immunofactor", which is a transfer factor specific for EBV, HHV-6 and CMV amongst other viruses, whereas the Fall 1998 edition of "Positive Health News" suggests a different intended product, denoted "Immunofactor 6", intended to be specific for HHV-6 subtypes. Accordingly, applicants maintain that the method of production and the literature of the field cited by the Examiner clearly distinguish between a transfer factor for multiple virus types and a transfer factor specific for HHV-6 subtypes.

Accordingly, applicants maintain that the rejected claims define an invention not obvious from the cited references, and therefore not properly rejected under 35 U.S.C. §103(a), and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections under 35 U.S.C. §102(b)

The Examiner stated that claims 32-40 and 42-43 are rejected under 35 U.S.C. §102(b) as being anticipated by an advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p. 29, in view of an advertisement by Chisolm Biological Laboratory in Positive Health News, Fall 1997,

p. 27.

The Examiner further stated that HHV6 strains A and B specific transfer factors had been manufactured and sold with the brand name as IMMUNFACTOR6 by Chisolm Biological Laboratory in 1998 (see page 29). The Examiner also stated that the pharmaceutical composition comprising the transfer factors is formulated as a simple dried colostrum/whey product in view of the same company's disclosure in the advertisement by Chisolm Biological Laboratory in Positive Health News, Fall 1997, p. 27

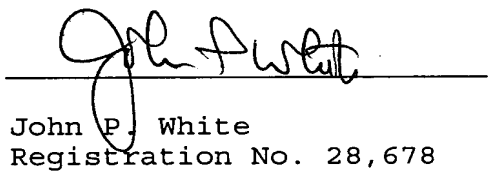
In response, applicants respectfully traverse the Examiner's rejection. Specifically, applicants note that the references cited by the Examiner do not teach the claimed invention. Applicants note that the Examiner's statement that the transfer factors (of Chisolm) are "formulated as a simple dried colostrums/whey product" is not consistent with the actual wording of the Fall 1997 Positive Health News advertisement. The Fall 1997 advertisement states that one should not "be fooled by simple dried colostrum/whey products", and contrasts such colostrum products with their own "Immunfactor" product. Accordingly, there is no indication in the advertisement that the "Immunfactor" product is "a cell free-fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6A lactating animal", and in fact the advertisement suggests the "Immunfactor" is not colostrum-based. Accordingly, applicants maintain that the cited reference does not teach all the elements of applicants' claimed invention.

Finally, with regard to claim 40, applicants note that the cited references nowhere disclose or suggest a method for treating chronic fatigue syndrome comprising administering the mammary gland secretion of a HHV-6A and the mammary gland secretion of a HHV-6B immunized lactating mammal.

Accordingly, applicants maintain that the claimed invention is not anticipated by the cited references, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

No fee, other than the enclosed total of $259.00, including a $44.00 claim fee and a $215.00 fee for a two month extension of time, is deemed necessary in connection with the filing of this Amendment. If any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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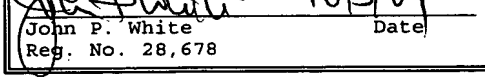

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